

**Remarks:**

Applicant has carefully studied the non-final Examiner's Action mailed 09/01/2004, having a shortened statutory period for response set to expire 12/01/2004, and all references cited therein. The amendment appearing above and these explanatory remarks are believed to be fully responsive to the Action. Accordingly, this important patent application is now believed to be in condition for allowance.

Applicant responds to the outstanding Action by centered headings and numbered paragraphs that correspond to the centered headings and paragraph numbering employed by the Office, to ensure full response on the merits to each finding of the Office.

***Priority***

1. Applicant's claim for the benefit of an earlier filing date stands objected to because the claim recites an incorrect parent application. Accordingly, paragraph [0002] has been amended to recite the correct parent application data. A corrected Application Data Sheet is filed herewith.

***Specification***

2. The abstract of the disclosure stands objected to because the embodiment of the invention described therein does not correspond to the embodiment of the invention described in the claims. This ground of objection is met by a carefully amended abstract of the disclosure.

3. The disclosure stands objected to because in paragraph [0008]. --slides-- should be inserted following "on," and because in paragraph [0028], "if" should be --of--. Paragraphs [0008] and [0028] have been corrected as required.

4. Applicant has checked the lengthy specification for other errors and two (2) additional errors were found in paragraphs [0046] and [0078] and are corrected herewith.

***Claim Objections***

5. Claim 1 stands objected to because in lines 5-6 and also in line 17 "that scrapes" should be --adapted to scrape--. The changes are made in claim 1, currently amended.

6. Claim 3 stands objected to because in line 2, "an" should be --said--. The change is made in claim 3, currently amended.

7. Claim 5 stands objected to because in claim 1, "means" should be deleted. The change is made in claim 5, currently amended.

***Claim Rejections – 35 U.S.C §102***

8. Applicant acknowledges the quotation of 35 U.S.C. §102(b)

9. Claims 1, 2 and 6 stand rejected under 35 U.S.C. §102(b) as being anticipated by Wang. Reconsideration and withdrawal of this ground of rejection is requested for the reasons that follow.

The Wang structure is distinctly different from the claimed structure. Sampling needle 14 has a non-beveled leading end that forms annular cutting edge 28. Lateral opening 34 has a recessed leading edge 38 that is recessed so that it performs no cutting during distal-to-proximal movement (retraction) of sample needle 14. Lateral opening 34 has a trailing cutting edge 36 that cuts tissue during proximal-to-distal (insertion) of sample needle 14. Thus, both Wang and Applicant provide two cutting edges during proximal-to-distal travel and no tissue or cellular material is cut during distal-to-proximal (retraction) of the needle.

However, Wang's sample needle 14 cannot be introduced into a patient's tissue because its leading end having annular cutting edge 28 formed therein cannot cut into said tissue because it is not beveled as is Applicant's leading end. Accordingly, inner needle 16 having sharp conical point 39 is introduced through the lumen of sample needle 14 and performs the initial puncturing of the skin; sample needle 14 then follows. Both cutting surfaces 28 and 36 are disabled when inner needle 16 is disposed within the lumen of sample needle 14. Thus, after the initial insertion is made, inner needle 16 is withdrawn and sample needle 14 is then reciprocated along its longitudinal axis.

Figs. 3 and 5 of Wang illustrate that second or trailing cutting edge 36 of Wang is a beveled edge that is sloped downwardly in a proximal-to-distal direction. The leading, recessed and therefore non-cutting edge 38 is sloped in an opposite direction, i.e., it is sloped downwardly in a distal-to-proximal direction. It follows that lateral opening 34 is a "V"-shaped opening and its "bottom" is half-way between its leading and trailing edges 38, 36, respectively. Still, said bottom is proximal to distal end 28.

However, due to the "V" shape of lateral opening 34, downwardly sloping second cutting edge 36 cannot slice off tissue at the cellular level as disclosed and claimed by Applicant. For a slice of tissue to be cut, it must have a thickness at least equal to the thickness of the sidewall of sample needle 14. If the tissue has a thickness that is any less, said tissue will not extend into lateral opening 34 and will not encounter cutting edge 36.

In sharp, distinct and patentable contrast, as depicted in Applicant's Fig. 9, sharp edge 20e slices off tissue at the cellular level because tissue that encounters said sharp edge 20e does

not have to extend into slot 18a by an amount equal to the thickness of the sidewall of Applicant's needle. This limitation is expressed in claim 1, currently amended, by the term "cellular material" because said term, when construed in conjunction with these remarks, is understood to mean material having a thickness less than that of a sidewall of a needle. Suppose Wang's lateral opening 34 (Fig. 3) were in the shape of an inverted "V"; if that were the case, then Wang's second cutting edge 36 would suggest Applicant's second cutting edge. However, by providing opening 34 in the form of a "V" as aforesaid and as clearly depicted, Wang clearly teaches away from Applicant's cutting edge capable of cutting material at the cellular level.

10. Claims 1, 2, 4 and 6 stand rejected under 35 U.S.C. §102(b) as being anticipated by De Santis. Reconsideration and withdrawal of this ground of rejection is requested for the reasons that follow.

U.S. patent No. 5,560,373 to De Santis et. al. does not disclose a sharp edge 128 adapted to scrape tissue at the cellular level when the needle is displaced in a proximal-to-distal direction. See Figures 19 and 20. Edges 124 and 128 are blunt and perform no cutting action. The first and second undercuts 122, 126 are recesses into which tissue is pulled under vacuum. Blunt edges 124 and 128 cooperate with undercuts 122, 126 to grab the tissue and to hold the tissue in the cavity, not to cut the tissue. All of the tissue pulled into the De Santis cavity by a vacuum is cut, not by blunt edges 124 or 128, but by advancing spring-loaded cannula 14 having cutting tip 135 over the needle in a proximal-to-distal direction. No material at the cellular level is obtained. Accordingly, said blunt tissue holders 124, 128 do not suggest or anticipate the claimed cutting edges of claims 1, 2, 4, and 6.

#### *Allowable Subject Matter*

11. Claims 3 and 5 stand objected to as being dependent upon a rejected base claim, and as being allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. New independent claim 7 includes the subject matter of base claim 1 and dependent claim 3, and new independent claim 8 includes the subject matter of base claim 1 and dependent claim 5. However, said dependent claims 3 and 5 are not cancelled and are allowable upon the allowance of claim 1, currently amended.

12. Applicant acknowledges the Office's statement of reasons for the indication of allowable subject matter. As stated in the preceding paragraphs, the invention is entitled to a broader scope than the scope recited in said statement of reasons.

***Conclusion***

13. Applicant agrees that the art made of record and not relied upon is not more pertinent to the claimed invention than the art cited.

14. If the Office is not fully persuaded as to the merits of Applicant's position, or if an Examiner's Amendment would place the pending claims in condition for allowance, a telephone call to the undersigned at (727) 507-8558 is requested. Applicant thanks the Office for its careful examination of this important patent application.

Very respectfully,

SMITH & HOPEN

By: 

Ronald E. Smith  
Suite 220  
15950 Bay Vista Drive  
Clearwater, FL 33760  
(727) 507-8558  
Attorneys for Applicant

Dated: November 24, 2004

pc: John S. Fisher, M.D.

---

**CERTIFICATE OF FACSIMILE TRANSMISSION**  
(37 C.F.R. 1.8(a))

I HEREBY CERTIFY that this Amendment A, including Introductory Comments, Amendments to the Specification, Amendments to the Claims and Remarks, is being transmitted by facsimile to the United States Patent and Trademark Office, Art Unit 3736, Attn: Mr. Charles Alan Marmor II, (703) 872-9302, on November 24, 2004.

Dated: November 24, 2004

  
Shelley Butz